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14. ABSTRACT Traumatic Brain Injury (TBI) has been referred to as the "signature injury" in Operations Iraqi Freedom and Enduring Freedom, and the Automated Neuropsychological Assessment Metrics (ANAM4), a brief computerized battery of neurocognitive tests, was mandated as a pre-deployment tool in 2008 to help evaluate the effects of TBI. Despite preliminary support for ANAM's correlation with traditional neuropsychological tests, little is known about what constitutes "normal" performance on ANAM4 among cultural/ethnic minority populations, despite their disproportionate representation in the military, the risk of TBI and PTSD during deployment, and the fact that demographic/cultural factors are known to influence performance on many neurocognitive tests. Because of the central role of normative data in interpreting neurocognitive test results, it is important to know whether existing norms are applicable to individuals with different sociocultural backgrounds. The goals of this study are to 1) establish preliminary normative data for ANAM4 in samples of healthy African American, American Indian, and Hispanic American subjects, and 2) compare the ANAM4 test battery with traditional neuropsychological tests that tap similar cognitive abilities. Milestones for Year 1 included obtaining and setting up equipment, pilot testing, staff training, and setting up the database. Our recruitment goal for Year 1 was 90, and we have completed data collection on 94. Milestones for Year 2 such as recruitment, testing, data entry and analysis are in progress.					
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Introduction

Traumatic Brain Injury (TBI) has been referred to as the “signature injury” in Operations Iraqi Freedom and Enduring Freedom, and the Automated Neuropsychological Assessment Metrics (ANAM4), a brief computerized battery of neurocognitive tests, was mandated as a pre-deployment tool in 2008 to help evaluate the effects of TBI. Despite preliminary support for ANAM’s correlation with traditional neuropsychological tests, little is known about what constitutes “normal” performance on ANAM4 among cultural/ethnic minority populations, despite their disproportionate representation in the military, the risk of TBI and PTSD during deployment, and the fact that demographic/cultural factors are known to influence performance on many neurocognitive tests. Because of the central role of normative data in interpreting neurocognitive test results, it is important to know whether existing norms are applicable to individuals with different sociocultural backgrounds. The goals of this study are to 1) establish preliminary normative data for ANAM4 in samples of healthy African American, American Indian, and Hispanic American subjects, and 2) compare the ANAM4 test battery with traditional neuropsychological tests that tap similar cognitive abilities. Milestones for Year 1 included obtaining and setting up equipment, pilot testing, staff training, and setting up the database. Our recruitment goal for Year 1 was 90, and we have completed data collection on 94. Milestones for Year 2 such as recruitment, testing, data entry and analysis are in progress.

Body

Year 1 funds acquired from the USAMRMC ORP HRPO September 2010. The approved project timeline is presented in TABLE 1.

TABLE 1: STATEMENT OF WORK: Study timeline

<u>Milestone</u>	<u>Base Line Plan Date</u>	<u>Act Comp Date</u>	<u>Remark</u>
Obtain and set up equipment, pilot testing	11-Jan-2011	27-Dec-2011	Reporting Period: 27-Sep-2010 thru 27-Dec-2010
Staff training and set up database	11-Jan-2011	27-Dec-2011	Reporting Period: 27-Sep-2010 thru 27-Dec-2010
Recruitment and testing of subjects	26-Oct-2012		In progress
Data entry	26-Oct-2012		In progress
Data analysis	26-Oct-2012		In progress

Administrative and Logistical Matters

IRB Approvals

- UTSW Medical Center IRB application completed and approved 8/27/2011.
- Choctaw Nation IRB application completed and approved 11/17/2010.
- Requested materials approved by USAMRMC ORP HRPO on 1/13/2011.
 - UTSW and Choctaw IRB Approval Letters
 - Study Protocol
 - Consent Form/HIPPA Form
 - Recruitment flyers for UTSW and Choctaw
 - Subject screening form (inclusion/exclusion criteria)
- UTSW Continuing Review approved 6/8/2011.
- Mid-Year Progress Report submitted to Choctaw Nation IRB 3/1/2011.
- Choctaw Nation Continuing Review submitted 9/9/2011, approved 9/28/2011.

Contracts

- Choctaw Nation subcontract developed, generated, and awarded to assist in the recruitment of American Indian subjects.
- Co-investigator subcontract developed, generated, and awarded to augment expertise in cross-cultural research methodology, and adaptations in telehealth and military mental health systems. Modification made to project budget to fund co-investigator one month in Year 1 and one month in Year 2.
- Dr. Harris consultant form completed and awarded to assist with minority recruitment, development of demographic questionnaire, and preliminary data interpretation.
- Dr. Hynan, biostatistical consultant, IDR form completed and submitted to assist with database development, management, and statistical analysis.

Meetings

- Study personnel met weekly with the PI to review progress over the course of Year 1.
 - Initial focus was on material acquisition and pilot testing, study paperwork, creating study questionnaires, and subject recruitment planning.
 - Once materials were acquired, questionnaires developed, and recruitment strategies outlined, emphasis was placed on database development.
 - In the second quarter meetings shifted back to subject recruitment.
- PI updated co-investigators on progress quarterly via emails and phone calls.
- PI met with Dr. Shore and Dr. Harris in Denver, Colorado, (where both are based) October 2011, to discuss preliminary data and recruitment strategies for Year 2.

Year 1 Milestones

Obtain and set up equipment –COMPLETED

TABLE 2: Equipment purchased and received for Year 1.

Equipment Purchased	Date Received
1- ANAM4 Software Program	10/18/2010
1- HP Laser Pro M1212nf MFP Printer	10/17/2010
3 Lenovo ThinkPad L512 Laptops	11/22/2010
50* - \$25 Participant Incentive Gift Cards	11/11/2010

*Gift cards – Listed in budget as participant cost 180@\$25.

- ANAM4 uploaded on laptops and study battery created. ANAM4 battery tested on all three laptops by coordinator.

Pilot testing- COMPLETED

Pilot testing of ANAM4 battery and traditional neuropsychological test battery initiated with healthy volunteers (students and staff members) at UTSW Medical Center.

Staff training and setup database - COMPLETED

- Kirstine Carter, student worker, trained on paper/pencil tests and ANAM4 battery.
- Meetings with Dr. Cullum (PI), Dr. Weiner (Co-PI), Dr. Hynan (Biostatistical Consultant), Shradhdha Joshi (Coordinator), and Kirstine Carter (Student Worker) to discuss database setup.
- Database setup and data dictionary created.

Recruitment and testing of subjects –IN PROGRESS

Recruitment strategies in Dallas, TX and Talihina, OK for Year 1.

- “Health Topics Survey Registry” at UTSW
 - The Registry was established as a project to evaluate challenges faced in recruiting subjects from a database. Registry personnel attend events in the community to recruit subjects for studies at UTSW. This was a very useful tool for Year 1 recruitment in Dallas.
- “Find a Clinical Trial” at UTSW website.
 - This website was developed to connect researchers and community members interested in participating in research studies.

- Community Colleges.
-Flyers about the study were placed at nine local colleges.
- Choctaw Nation Health Services Authority Clinics.
- Located in Talihina, Idabel, McAlester etc.
- Community Health Fairs.
- Flyers about the study were distributed at minority health fairs.
- Advertising in the Choctaw newspaper “Bishinik.”
-The newspaper is sent to Choctaw Tribe members in the United States.

Year 1 recruitment numbers.

- 378 recruitment letters were sent by “Health Topics Survey Registry.”
- 174 subjects were screened for Year 1 of these, 164 subjects were eligible, though many did not show up for appointments.
- 94 subjects tested for Year 1.

TABLE 3: Number of subjects tested by race/ethnic group for Year 1.

<u>Group</u>	<u>Goal</u>	<u>Actual</u>
African American	30	38
American Indian	30	24
Hispanic American	30	32
Subtotal	90	94

Recruitment challenges for Year 1.

- Approximately 45% no-show rate.
-Two more attempts were made to get subjects in for a study visit.
- Many eligible subjects declined to participate in the study because they felt the participation incentive was low.

Recruitment and testing will continue in Year 2.

Data entry-IN PROGRESS

Data for Year 1 were collected, scored, double scored, and entered by two data operators. Year 2 data entry is in progress.

Data analysis –IN PROGRESS

Data for Year 1 were reviewed and analyzed in preliminary fashion in the fourth quarter by study P.I.'s.

Key Research Accomplishments

Key research accomplishments for Year 1 include:

- Obtaining and setting up equipment.
- Pilot testing.
- Staff training.
- Database setup and data dictionary generated.
- Data entry and cleaning for Year 1.
- 94 subjects tested for Year 1.
- UTSW Continuing Review approved for Year 2.
- Choctaw Nation Continuing Review approved for Year 2.

Reportable Outcomes

Data collection is still in progress; no reportable outcomes to date.

Conclusion

Preliminary examination of Year 1 data looks promising vis-a-vis hypothesis I, as the groups are performing at similar levels across most of the primary ANAM4 composite scores. Some differences between groups were seen on certain subtests, but whether this finding will remain upon completion of the full sample remains to be seen. Initial results also look generally similar to other published normative studies of ANAM, although our groups are scoring lower on some measures. Recruitment, testing, and data entry are currently underway for Year 2.

References

N/A

Appendices

N/A